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BRIVANT MEDICAL ENGINEERING

CPS Courier Guidewire
Special 510(k)

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

(1) Submitter's Name / Contact Person: Brivant Limited,
Parkmore West Business Park
Galway,
Ireland

JAN - 9 2008

Contact Person: Tomas Furey,
Vice President Regulatory Affairs
Tel: +353 91 385037
Fax: +353 91 766598

(2) Summary Preparation Date: October 25, 2007

(3) Device Name and Classification:

Trade Name:

CPS Courier Guidewire, Extra Firm, Straight Tip. Catalogue Number: 901008-01

CPS Courier Guidewire, Extra Firm, J Tip. Catalogue Number: 901008-02

CPS Courier Guidewire, Firm, Straight Tip. Catalogue Number: 901008-03

CPS Courier Guidewire, Firm, J Tip. Catalogue Number: 901008-04

CPS Courier Guidewire, Medium, Straight Tip. Catalogue Number: 901008-05

CPS Courier Guidewire, Medium, J Tip. Catalogue Number: 901008-06

CPS Courier Guidewire, Soft, Straight Tip. Catalogue Number: 901008-07

CPS Courier Guidewire, Soft, J Tip. Catalogue Number: 901008-08

CPS Courier Guidewire, Extra Soft, Straight Tip. Catalogue Number: 901008-09

CPS Courier Guidewire, Extra Soft, J Tip. Catalogue Number: 901008-10

Common Name: Guidewire

Classification Name: Catheter, Guidewire

Device Classification: Class II, 21 CFR §870.1330

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MEDICAL ENGINEERING

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(4) Summary of Substantial Equivalence

The CPS Courier guidewires have minor design differences with the predicate Brivant guidewire. The Brivant Guidewire has the same intended use and fundamental technology as the predicate Brivant Guidewire. The technical features are closely similar and where there are differences these differences are minor such that they do not affect safety or effectiveness and there is also supporting data to demonstrate that the new technical features have not diminished safety or effectiveness - as a result the CPS Courier Guidewire is substantially equivalent to the Brivant Guidewire predicate.

(5) Description of the Device:

The Courier Guide wire is a disposable medical device designed for single use only. It consists of a 0.014" diameter stainless steel core wire, the distal end of which is reduced in diameter in a progressive fashion through a centreless grinding operation. The profile of this reduced section affords the product a reduced area of stiffness. The guide wire comes in 5 unique base models distinguished by their distal flexibility portions, the profile varied to provide a range of products of mixed stiffness. This reduced section is covered with a polymer coating of equivalent diameter to the main core body. Underneath the polymer at the distal tip there is a 0.010" platinum/tungsten alloy platinum coil attached to the distal tip of the core by means of solder joints. This provides greater visibility on x-ray equipment.

(6) Statement of Intended Use:

The CPS Courier Guidewires are intended for use in the coronary and peripheral vasculature.

(7) Technological Characteristics.

Comparisons of the proposed and predicate device show that the technological characteristics such as materials, performance characteristics, sterilization and packaging are substantially equivalent to the currently marketed device.

(8) Summary of Testing:

Performance testing involving the following testing has been completed tensile strength, torque strength, torque response, coating performance, radiopacity, tip flexibility, catheter compatibility testing, accelerated aging and biocompatibility testing in compliance with ISO 10993-1 has been successfully completed. The successful tests demonstrated the CPS Courier Guidewires consistently performed within their design parameters, are safe and effective and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

Brivant, LTD
c/o Mr. Thomas Furey
Vice President Regulatory Affairs
Parkmore West Business Park
Galway,
Ireland

Re: K073082
Trade Name: CPS Courier Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: December 18, 2007
Received: December 20, 2007

Dear Mr. Furey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K073082

Device Name: CPS Courier Guidewire

Indications for Use:
The CPS Courier Guidewires are intended for use in the coronary and peripheral vasculature.

Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over the Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073082